REMARKS

Applicants first wish to thank Examiners Harris and Caputa for the very helpful interview conducted on December 2, 2003 and they present in this reply the amendment discussed in that interview.

Claims 1, 3-37, 39, 40, and 42-44 are pending. Claims 5-37 are withdrawn from consideration. Claims 1, 3, 4, 39, 40, and 42-44 were rejected under 35 U.S.C. § 112, first paragraph, and claim 43 was rejected under 35 U.S.C. § 102. Applicants address each of these rejections as follows.

Claim Amendments

Applicants have amended claims 1 and 43. Claims 3, 5-37, 39, 40, and 44 have been canceled. Support for the amendment to claim 1 may be found, for example, at page 3, lines 25-27, page 5, lines 14-18, and page 12, lines 15-18, of the specification. Claim 1, as amended, recites the DSMZ accession numbers for cell lines 23132 and 3051. These accession numbers are also recited in the specification, for example, at page 5, lines 12-16, and page 12, lines 15-18. Applicants note that the DSMZ (Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH) is an International Depositary Authority established under the Budapest Treaty, and, therefore, is an acceptable depository under 37 C.F.R. § 1.803. No new matter has been added by this amendment.

Rejection under 35 U.S.C. § 112, first paragraph

Claim 1 was rejected under 35 U.S.C. § 112, first paragraph, as containing new matter and claims 1, 3, 4, 39, 40, and 42-44 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 3, 39, 40, and 44 have been canceled and the rejection of these claims, therefore, is moot. Applicants have deleted the phrase "stomach carcinoma cell" from claim 1, and submit that claim 1, as amended, does not contain new matter. This basis for the rejection should be withdrawn.

The 35 U.S.C. § 112, first paragraph written description rejection, as directed to the present claims, should also be withdrawn. The standard for adequate written description is whether the description clearly allows persons of ordinary skill in the art to recognize that one has invented what is claimed (see, e.g., M.P.E.P. (Eighth Edition, Rev. 1, February 2003) § 2163.02). In applying this standard, the Federal Circuit has held:

> If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met. *In re Alton*, 76 F.3d 1168, 1177, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996).

Applicants' specification clearly meets this standard for the presently claimed invention. The structure of human CD55 was known in the art at the time the present application was filed. Further, as taught, for example, at page 5, lines 12-18, of the specification, Applicants determined that a CD55 protein with a tumor-specific glycostructure, as presently claimed, has a molecular weight of about 82 kD. Medof et al. (J. Exp. Med. 160:1558-1578, 1984; "Medof"), which was cited in the last Office Action, teaches a DAF/CD55 protein that was purified from the stroma of human red blood cells and has a molecular weight of 70 kD (see Figure 2). As human red blood cells are not tumor cells, the CD55 protein expressed by these cells cannot have a tumor-specific glycostructure. The 70 kD CD55 protein described by Medof is clearly different from Applicants' 82 kD CD55 protein having a tumor-specific glycostructure.

Moreover, antibodies that recognize the CD55 primary structure, and thus recognize both wild-type and tumor-specific forms of CD55, were commercially available at the time the present application was filed. Consequently, based on the description provided in Applicants' specification, one skilled in the art can readily distinguish CD55 lacking a tumor-specific glycostructure from one containing such a glycostructure. Thus, given that the present claims require the claimed glycoprotein to not only have the primary structure of human CD55, but also a tumor-specific glycostructure and an apparent molecular weight of about 82 kD, the presently claimed glycoprotein is clearly described in Applicants' specification. This basis for rejection should be withdrawn.

Rejection under 35 U.S.C. § 102

Claim 43 was rejected under 35 U.S.C. § 102(b) as being anticipated by Medof as evidenced by Hensel et al. (Cancer Res. 59:5299-5306, 1999; "Hensel") and by Tsuji (U.S. Patent No. 5,695,945; "Tsuji") as evidenced by Hensel. Applicants submit that the present claims are free of this rejection.

Neither Medof nor Tsuji teach a CD55 protein with a tumor-specific glycostructure, much less one that has an apparent molecular weight of about 82 kD as required by the present claim. In addition, these references fail to teach a CD55 protein which, when bound by an antibody, results in apoptosis of a cell, as required by claim 43.

Medof teaches incorporation of a purified DAF/CD55 into red blood cells (erythrocytes) and its effect on hemolytic activity. The DAF/CD55 was purified from the stroma of human red blood cells and has a molecular weight of 70 kD (see Figure 2). As human red blood cells are not tumor cells, the CD55 protein expressed by these cells cannot have a tumor-specific glycostructure. Also, hemolysis is distinct from apoptosis.

Tsuji raised anti-DAF antibodies using DAF purified from erythrocyte membrane. Again, the DAF protein described by Tsuji is obtained from non-tumor cells and has a molecular weight of 70 kD (see e.g., column 4, lines 5-8). Thus, this DAF, like the one described by Medof, cannot contain a tumor-specific glycostructure. Further, Tsuji fails to teach that binding DAF induces apoptosis in a cell.

With regard to the Hensel reference, Applicants note that this reference was published after the December 22, 1998 priority date of the present application. A certified copy of this German application (German Patent Application No. 198 59 248.5), as well as its translation, were submitted to the U.S. Patent and Trademark Office in Applicants' December 3, 2001 reply to the Office Action mailed on July 3, 2001. Applicants draw the Examiner's attention to page 5 of the translation, where it is stated that the isoform of CD55 which is specific to gastric carcinomas has a relative molecular weight of 82 kDa. This isoform of CD55 is nowhere taught by Medof or Tsuji.

For all of the above reasons, Applicants submit that the present claims are free of the cited references. The 35 U.S.C. § 102(b) rejection of claim 43 should be withdrawn.

CONCLUSION

Applicants submit that the application is now in condition for allowance and this action is hereby requested.

Enclosed is a Petition to extend the period for replying to the Office Action for one month, to and including December 26, 2003, and an authorization to charge the required extension fee to Deposit Account No. 03-2095.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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